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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/381,372	09/20/1999	TOSHIKAZU KAWAI	3007/48236	3875

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EXAMINER	
KEYS, ROSALYND ANN	
ART UNIT	**PAPER NUMBER**
1621	5

DATE MAILED: 03/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/381,372	Applicant(s) KAWAI ET AL.	
	Examiner Rosalynd Keys	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-11 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Claims

1. Claims 1-11 are pending.

Claims 1-11 are rejected.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on March 3, 1998. It is noted, however, that applicant has not filed a certified copy of the foreign application as required by 35 U.S.C. 119(b).

Information Disclosure Statement

3. The information disclosure statement filed September 20, 1999 has been considered.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawai et al. (EP 0 703 450 A1) alone or in view of Ryan (WO 97/25303).

Kawai et al. teach a process for removing the acid component or non-reacted 1,1,1,3,3,3-hexafluoroisopropyl alcohol (HFIP) from the crude fluoromethyl 1,1,1,3,3,3-hexafluoroisopropyl ether (sevoflurane) by contacting it with an aqueous solution of an alkali metal compound (see page 3, line 58 to page 4, line 3). The concentration of the alkali aqueous solution can be from 0.01 to 10-wt% (see page 4, lines 4 and 5). The temperature of the treatment is usually from 0 to 60°C (see page 4, lines 5-7).

Kawai et al. fail to teach the amount of HFIP present in the crude sevoflurane. However, it appears from the teachings of Kawai et al. that the amount of HFIP is not critical and that the treatment will be effective at removing unreacted HFIP regardless of

the initial concentration of unreacted HFIP. Of course one having ordinary skill in the art at the time the invention was made would have been motivated to obtain sevoflurane containing no unreacted HFIP or reduced amounts of the unreacted HFIP, since sevoflurane is useful as an inhalation anesthetic. Thus, as taught by Ryan the reaction between the starting materials can be readily carried out to result in complete conversion of the HFIP (see page 2, lines 15-23). Thus, based on the teachings of Ryan one having ordinary skill in the art would have found it obvious to modify the concentration of HFIP present in the sevoflurane of Kawai et al. by varying the reaction conditions. Further, changes in concentrations of an old process do not impart patentability unless the recited ranges are critical, i.e., they produce a new and unexpected result . *In re Aller et al.,* (CCPA 1955) 220 F2d 454, 105 USPQ 233.

Kawai et al. further differ from the instant claims in that Kawai et al. fail to disclose the ratio of the basic substance to HFIP. However, it is well established that merely selecting proportions and ranges is not patentable absent a showing of criticality. In re Becket, 33 U.S.P.Q. 33 (C.C.P.A. 1937). In re Russell, 439 F.2d 1228, 169 U.S.P.Q. 426 (C.C.P.A. 1971).

The examiner has considered the comparative examples disclosed on pages 12 and 13 of the instant specification. However, these comparative examples were not sufficient to avoid a rejection over the prior art cited above because the comparisons are not being made with the closest prior art of record, i.e., Kawai et al. (EP 0 703 450 A1), specifically example 6 . In comparative examples 1 and 2 of the instant specification the crude sevoflurane is being treated with pure water, whereas Kawai et

al. teach the use of a basic substance as claimed. In comparative example 3 the amount of HFIP is reduced from 5% to 0.05%, which the examiner considers to be significant reduction, nonetheless the treatment was conducted at a temperature of 70°C, whereas Kawai et al. teach the use of temperatures between 0 and 60°C, specifically 40°C in example 6. Further, the examiner does not see how the instant invention is unobvious over comparative example 3.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosalynd Keys whose telephone number is 703-308-4633. The examiner can normally be reached on M-F 5:30 a.m.-10:30 a.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 703-308-4532. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Rosalynd Keys
Primary Examiner
Art Unit 1621

R. Keys
March 25, 2002